Certificate

TÜVRheinland®

Certificate No.:	MD 1804155 3287531-130
Manufacturer:	**Dominion Biologicals Limited** 5 Isnor Drive Dartmouth, Nova Scotia B3B 1M1 Canada
D-U-N-S No.:	20-727-3194
Certification criteria	ISO 13485:2016 Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009 Canada Medical Devices Regulations – Part 1 – SOR 98/282
Scope:	Design and manufacture of blood grouping reagents – murine monoclonal; blood grouping reagents – Rh monoclonal; diluent control; anti-human globulin (murine monoclonal); blood grouping reagent – Human monoclonal IgM; serological reagent - potentiators; serological blood grouping reagent – lectins; ELU KIT PLUS red cell elution system and blood grouping reagent (micro) for Galileo neo.

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.:	60239253-001
Issue Date:	2019-05-29
Effective Date:	2019-05-29
Expiry Date:	2020-12-31

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dr. H. Lüdemann
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on www.certipedia.com, via the QR code or calling 1-888-743-4652.

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